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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,904	11/30/2001	Harold R. Garner	119929-1037	4132

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EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/998,904	GARNER ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-213* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-213* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-57 and 203-204, drawn to a method to predict single nucleotide polymorphisms, and a computer program for running the program, classified in class 702, subclass 20.

II. Claims 58-181, drawn to methods to creating a variation or polymorphism predictiveness value , classified in class 702, subclass 20.

III. Claims 182-195, drawn to methods of creating a variation or polymorphism predictiveness matrix, classified in class 702, subclass 20.

IV Claims 196-197 and 207, drawn to an isolated nucleic acid comprising a single nucleotide variation or polymorphism, classified in class 536, subclass 23.1.

V. Claims 198-202, drawn to an apparatus comprising a substrate and one or more isolated nucleic acids, classified in class 536, subclass 23.1.

VI. Claims 205-206, drawn to a polymorphism predictive dataset, classified in class 702, subclass 20.

VII. Claims 208-210, drawn to a method to predict single nucleotide polymorphisms comprising different steps than those of Group I, classified in class 702, subclass 20.

VIII. Claim 211, drawn to an isolated nucleic acid comprising a recited SEQ ID NO., classified in class 536, subclass 23.1.

IX. Claims 212-213, drawn to an isolated nucleic acid comprising a cardiomyopathy disease-related SNP, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of the different Inventions recite different method steps and are directed to different results. While the value predicted by the method of Group II may be used in the matrix in the method of Group I, it is not limited to be one for such a use, nor is the matrix in the method of Group I limited to comprise the value predicted by the method of Group II. For these reasons, Groups I and II are separate and distinct.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of the different Inventions recite different method steps and are directed to different results. While the matrix created by the method of Group III may be used in the method of Group I, it is not limited to be one for such a use, nor is the matrix in the method of Group I limited to be one created by the method of Group III. For these reasons, Groups I and III are separate and distinct.

Inventions I and IV are related as process of "making" and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of Group I is not actually a method of production, but is an in silico method of predicting a sequence variance. The nucleic acids of Group IV are physical entities and may be produced synthetically (i.e. by a synthesizer) or recombinantly (e.g. by a cell).

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a method and an apparatus which neither performs the method steps nor creates a matrix for use in the method of Group I. As the physical apparatus of Group V does not appear to be capable of using or being used by the method of Group I, the Groups are not related.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the dataset of Group VI Is not limited to be one for use in the method of Group I and the method of Group I is not limited to use the dataset of Group VI.

Inventions I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods reciting different steps and using different products. In addition, each method may be practiced without knowledge of or reference to the steps or results of the other method.

Invention I is not related to either of Inventions VIII or IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acids of Groups VIII and IX are not predicted by the method of Group I, are not produced by the method of Group I, and the method of Group I Is not directed to use of any of the nucleic acids of Groups VIII or IX.

Inventions II and III are separate and distinct. The methods of the Groups are directed to different results and recite different steps. Although the value predicted by the method of Group II may be used in the matrix created in the method of Group III, it is not limited to be created for use in the method or matrix of Group III. Similarly, the method of Group III is not limited to use the value of Group II, nor is the matrix created by the method of Group III limited to comprise the value created in the method of Group II. For these reasons, Groups II and III are separate and distinct.

Neither of Groups II or III is related to any of Groups IV, VIII or IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Groups II and III do not produce or use the nucleic acids of Groups IV, VIII or IX. As the nucleic acids of Groups II, VIII, and IX are physical products, they would not be expected to be useful in the in silico methods of Groups II and III. For these reasons, neither of Groups II or III is related to any of Groups IV, VIII, or IX.

Neither of Groups II or III is related to any of Groups V or VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Groups II and III do not recite use of either the apparatus or dataset of Groups V and VI, nor production of the dataset of Group VI. The apparatus of Group V is not limited to be one for use in either of the methods of Groups II or III, nor is it limited to be an apparatus for performing either of the methods of Groups II or III. The dataset of Group VI is not limited to be one for use in either of the methods of Groups II nor is the dataset limited to be one created by either of the methods of Groups II or III. For these reasons, neither of Groups II or III is related to either of Groups V or VI.

Neither of Groups II or III is related to Group VII. Neither of Groups II or III is related to any of Groups IV, VII or IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Groups II and III recite different steps and are directed t a different result than the method of Group VII. The method of Group VII does not recite use of either the value or matrix created in the methods of Groups II and III. In addition, the method of Group VII may be performed without knowledge of or reference to the steps or results of either of Groups II and III.

Each of Inventions IV and VIII-IX is separate and distinct from Invention V. Although the apparatus of Invention V is limited to comprise one or more nucleic acids with properties similar to those of Group IV, the nucleic acids attached to a matrix in Group V are nit limited to be that of Group IV. The nucleic acids of Groups VIII and IX do not appear to have properties similar to those in the apparatus of Group V. Further, it is noted that the apparatus of Group V may comprise a plurality of nucleic acids. An array, or plurality attached to a matrix, of nucleic acids would be expected to comprise different properties and produce different results in a method of use than would a single nucleic acids, as recited in Groups IV and VIII-IX. For these reasons, Groups V is separate and distinct from each of Groups IV and VIII-IX.

Groups IV and VIII-IX are not related. Each nucleic acid sequence represents a different structure, with properties necessarily different from that of any other nucleic acid sequence. As each of Groups IV and VIII-IX is directed to a different nucleic acid, each is directed to a separate and distinct product, therefore the Groups are not related.

Group VI is not related to any of Groups IV or VIII-IX. The dataset of Group VI does not comprise a physical product, but appears to be directed to virtual sequences and an associated value. As such, the dataset would be expected to have different properties than the physical

products of Groups IV and VIII-IX, and would be expected to behave differently in methods of use. For these reasons, Groups IV is not related to any of Groups IV and VIII-IX.

Group VII is not related to any of Groups IV or VIII-IX. The method of Group VII is not limited to use, identify, or produce any of the nucleic acids of Groups IV and VIII-IX, and none of the nucleic acids of Groups IV and VIII-IX is limited to be one produced by or used in the method of Group VII.

Groups V and VI are not related. The apparatus of Group V is a physical apparatus comprising actual nucleic acids whereas the dataset of Group VI appears to be a virtual product comprising nucleic acid sequence information. AS the products are different physically and comprise different kinds of information, they would be expected to have different properties and would be expected to behave differently in methods of use.

Group VII is not related to either of Groups V or VI. The method of Group VII does not recite use of either the apparatus of Group V nor the dataset of Group VI, and neither the apparatus nor dataset are limited to be one for use in the method of Group VII.

Because these inventions are distinct for the reasons given above and the search required for Groups II-IX is not required for Group I, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

(A) a single chemical modification (an exemplary list is set forth in claim 3);

(B) a single method of determining a variation or mutation frequency; e.g. as set forth in claims 11-21 and 126-136;

(C) a single method of adjusting a variation or mutation frequency; e.g. as set forth in claims 22-36 and 137-151;

(D) a single variation or mutation (see claims 88-101 and 152-165);

(E) a single limitation for what the nucleic acid or codon comprises (see claims 105-110, 113-115, 169-175 and 177-179).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from EACH of groups A-E, above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 4-8, 45-48, 52-59, 102-104, 116-123, 166-168, 180-182, 185-186, 189-191, 196-213 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Sequence Election Requirement Applicable to All Groups

In addition, some Groups detailed above read on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences and each unrelated sequence is considered a separate and distinct product, therefore a further restriction is applied to each Group. For an elected Group drawn to either amino acid or polypeptide sequences, the applicant must further elect a **single** amino acid or a **single** polypeptide sequence. (See MPEP 803.04). Due to the increasingly large size of sequence databases which must be searched and the increasing numbers of applications requiring sequence searches, it creates an undue burden on the Office to search more than a single sequence (product) per application. For these reasons, the requirements of 37 CFR 1.141 et seq. are no longer waived and applicant is required to elect a single sequence for examination. Applicant is reminded that this is a restriction requirement, not an election of species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention and the SEQ ID number to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER
Marjorie A. Moran

mam